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August 18, 2003

Marianne L. Horinko, Acting Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

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Subject: Comments on the HPV Test Plan for the Category Chloronitrobenzenes

Dear Administrator Horinko:

The following comments on Solutia's test plan for the Chloronitrobenzenes category are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Solutia, Inc. submitted its test plan on April 23, 2003 for the category Chloronitrobenzenes consisting of Benzene, 1-Chloro-2-Nitro- (CAS No. 88-73-3), Benzene, 1-Chloro-3-Nitro- (CAS No. 121-73-3) and Benzene, 1-Chloro-4-Nitro- (CAS No. 100-00-5), also known as ONCB, MNCB, and PNCB, respectively. All three members of the Chloronitrobenzenes category are manufactured in the U.S. by Solutia at a single site. Chloronitrobenzenes are then sold to a limited number of customers for the express purpose of full chemical conversion into other industrial chemicals that are ultimately used in the preparation of dyes and pigments, pesticides, animal feed ingredients, polymer additives, veterinary pharmaceuticals, and water-treatment chemicals. Solutia has submitted a comprehensive analysis of Chloronitrobenzenes by compiling substantial amounts of existing data from a variety of sources. In addition, this company combined three Chloronitrobenzene isomers with similar chemical, pharmacological, and toxicological properties into a single category for purposes of the HPV program. This approach demonstrates a thoughtful analysis by Solutia, in addition to being a scientifically valid analysis of a chemical's toxicity and adequate for a screening level program. Information from existing data or data derived from estimation models for physicochemical properties, environmental fate, and human and environmental effects of the three Chloronitrobenzene isomers have led Solutia to conclude that no additional testing is necessary under the HPV Challenge program.

Comparative investigations of the three Chloronitrobenzene isomers show a similar mode of action with the order of potency to be: para isomer > meta isomer >> ortho isomer. Toxicity information on PNCB, the most toxic of the three isomers, and ONCB is available for all SIDS endpoints in the HPV program. Some of the endpoints for MNCB have been appropriately filled using a "read-across" approach based on extensive information on para and ortho isomers. We commend Solutia's efforts in drawing on all available information from a myriad of sources to meet the SIDS endpoints for the chemical category Chloronitrobenzenes. This approach is consistent with the EPA's stated goals of maximizing the use of existing data in order to limit additional animal testing. We would also like to point out, as Solutia has in their test plan, that there are marked species differences in susceptibility to Chloronitrobenzene toxicity, i.e. their ability to form methemoglobin. Humans are decidedly more affected than rodent species and toxicity tests in rodents are NOT considered fully representative of the high acute toxicity to humans elicited by these chemicals. Furthermore, there is sufficient experience with occupational exposure in humans that a TLV has been established for PNCB. Additional testing in animals will not further protect humans, and the TLV is adequately protective.

We applaud Solutia on a well-written, thorough test plan for the category Chloronitrobenzenes and concur that no additional testing is needed for the purposes of the HPV program. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at meven@pcrm.org.

Sincerely,

Megha Even, M.S.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Research